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Prakash Kadkade

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EXAMINER

WARE, DEBORAH K

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/015,939	Applicant(s) KADKADE, PRAKASH	
	Examiner DEBBIE K. WARE	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 22, 23, 25, 61-63 and 65-75 is/are pending in the application.
- 4a) Of the above claim(s) 22, 23, 25 and 71-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 61-63, and 65-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8, 22-23, 25, and 61-63, 65-75 are pending.

Response to Amendment

The amendment filed January 16, 2009, and response filed September 25, 2008, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 27, 2007 and March 7, 2007 were received and entered. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. Per clarification request of consideration of IDS statements, the IDS(s) have/has been considered.

Election/Restrictions

Applicant's election of Group I in the reply filed on August 31, 2007, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22-23, 25 and 71-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 31, 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 61-63 and 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panis et al in view of Fretz et al, EP 0 147 236, Cino et al and Goodrich Jr. et al (US Patent No. 5,800,978 cited on a previously submitted PTO-892 Form).

Claims are drawn to a method for recovering plant cells from cryopreservation comprising obtaining cryopreserved plant cells, thawing the cells, washing the cells in a medium comprising at least one cryoprotectant agent in successively reduced concentrations, and said medium also containing a stabilizer and further removing the cryoprotective agent and recovering the thawed plant cells. The plant cells can be of the genus species *Taxus brevifolia* or *Musca* or *Picea* or *Daucus* or *Catharanthus*. The agent can be glycerol or DMSO in a concentration of about 0.5

Art Unit: 1651

M to 2 M and present in a concentration of from about 5% to about 20% by weight.

Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute or can be at about 140 degrees Celsius per minute.

Panis et al teach obtaining cryopreserved plant cells, thawing the cells, and recovering the thawed plant cells, see page 337, all lines and entire document. The plant cells can be of the genus *Musca* or *Picea* or *Daucus* or *Catharanthus*, see pages 339, line 6, page 343, line 3, page 345, line 21, and page 348, lines 1-20. Also a regrowth step can be carried out by the process, see page 337, line 24. The agent can be a carbon source such as glycerol or it can be DMSO, wherein the agent is in a concentration of about 0.5 M to 2 M and present in a concentration of from about 5% to about 20% by weight, see page 340, lines 35-50. Thawing takes place at a rate of at least about 30 degrees Celsius to about 60 degrees Celsius per minute, see page 340, line 7. MS-salts are used for recovery also, page 340, line 22. Removal of the agent by washing is disclosed at page 340, lines 7-8. Thawing can occur above 40 degrees Celsius, see page 337, line 20.

Panis et al does not disclose incubation technique in a medium containing cryoprotectant and stabilizer or use of *Taxus brevifolia* plant cells.

Fretz et al teach incubation after thawing for regeneration of plant cells, see page 141, lines 1-21. Fretz et al at page 142, column 1, line 36, teach plating the thawed plant cells.

Art Unit: 1651

EP Patent 0 147 236 teaches regeneration of plant cells in a medium containing a stabilizer, such as silver nitrate and other well known inhibitors, and carbon sources such as sugars, note pages 6-7, all lines.

Cino et al teach a medium and culture therefore, of *Taxus brevifolia* cells, see column 2, lines 46-47.

Goodrich Jr. et al teach washing the cells after thawing, note column 31, lines 44-46.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a method for the recovery of cryopreserved plant cells as disclosed by Panis et al, using the washing technique of newly cited Goodrich Jr. et al and techniques of Fretz et al on a regeneration medium containing a stabilizer as disclosed by the EP Patent and further to select for *Taxus* plant cells as disclosed by Cino et al. The presence of cryoprotectants as disclosed by Panis et al in the medium of the EP Patent would have been expected to work because these agents can be selected from sugars and the medium of the EP Patent clearly teaches the presence of sugars to provide for a successful combination of ingredients for the recovery of plant cells. It should be noted that sugars are encompassed by cryoprotectants. To reduce the amounts of the cryoprotectants in the media via washing the cells after thawing is clearly within the skill of an ordinary artisan as disclosed by Goodrich Jr. et al.

One of skill in the art would have expected successful results with the combination of stabilizer and cryoprotectant in a medium because these two ingredients

Art Unit: 1651

are disclosed by the cited prior art combination to be useful for recovering plant cells.

The process steps are disclosed by Panis et al Goodrich Jr. et al and Fretz et al obtaining cryopreserved plant cells, thawing, washing, and removal of cryoprotectant and recovering thawed plant cells. The cells are not disclosed by the art to have been genetically or phenotypically altered in any way.

Further, the thawed cells are plated on a medium as disclosed by Fretz et al, see page 142, line 36. In addition, the cells can be pretreated. Further to select for a heating temperature of about 140 degrees Celsius is well within the skill of an artisan who is capable of ascertaining such optimal conditions. Also Panis et al clearly teach thawing temperatures of 40 degrees Celsius and above, see page 337, all lines. Successful results would have been expected based upon the reading of the combination of cited prior art. In the absence of convincing and persuasive evidence to the contrary the claims are deemed prima facie obvious.

Response to Arguments

Applicant's arguments filed September 25, 2008, have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case,

Art Unit: 1651

washing is disclosed to be carried after thawing which means that the cells are thawed cells. The Declaration by Dr. Horn udner 37 CFR 1.132 is noted and while there is merit to the point that one of skill might reasonably expect cryopreservation to perform differently for animal cells versus plant cells, the washing step is a standard step and would be expected to be used similarly for both animal cells and plant cells because it is performed after cryopreservation.

The argument that the steps of the claimed process are not disclosed by the cited prior art is noted, however, the steps Applicants have set forth are well known and if the references are silent with respect washing in a medium having “successively reduced concentrations of cryoprotectant” this alone does not obviate the applied references. One of skill would have been motivated to reduce the concentration of cryoprotectant agent during washing in order to simplify and provide for a more economical and streamlined process for carrying out the washing steps. Goodrich clearly teach that the washing of cells is carried out via a series of dilutions which in and of itself suggests varied concentration of washing solutions. In order to optimize the recovery of plant cells one of skill in the art would have been motivated to provide for a cryoprotectant agent in amounts of reduced concentration since the effect would be the same at a constant concentration for cell recovery, therefore, in order to streamline the process one of skill would desire to use lower concentrations, especially since more than one washing is performed. The step of washing thawed cells is clearly well known in the art.

Thus, the prior art taken together as a combination with the teachings of Panis et al does suggest a need for multiple washings of the thawed cells. Furthermore, the argument that Panis et al teach an evaluation of the effects of different concentrations of cryoprotectants in the freezing process and not the washing step, it should be noted that the step of washing cells with cryoprotectant is well known and one of skill would have been motivated to modify Panis et al and thus, to apply the effects of differing concentration of cryoprotectants on the step of washing. Also Applicants point to a teaching by Panis et al wherein the cells become white so one would not want to combined Panis et al with the other cited references, however, DMSO is a cryoprotectant and as pointed out by Applicants it has proven to play a protective role during post-thaw. Thus, one of skill would have expected DMSO to provide successful results for its application during washing thawed cells since the cells would be in a post-thaw state and DMSO have proven to be useful. Further, the teaching that washing can impair cells and that removal of the cryoprotectant resulted in loss of regrowth only promotes the premise that the cryoprotectant would be expected to provide successful results in washing solutions, and to reduce its concentrations but not remove it completely would optimize growth of recovered cells.

The argument that one of skill would not be motivated by the cited applied art is noted, however, although the cells are different the steps and their applications are the same and applied for the same purpose and would have been expected to provide successful results for any cell type under suitable conditions. Also, while the declaration already addressed and made of record, states that results for animal cells are not

Art Unit: 1651

predicative of results obtained with plant cells is true, the cited combination of prior art clearly teaches that use of a cryoprotectant provides a protective effect for plant cells. Therefore, one of skill would be able to predict successful results under suitable conditions.

In response to applicant's reference to the Federal Circuit Court and argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Again although the declaration as referred to by Dr. Horn is accurate with respect to performance of cryopreservation technique on animal cells and plant cells to be different, as mentioned above washing the cells after thawing is clearly taught and there is no reason that one of skill would not expect this standard technique to work on plant cells especially since cryopreservation would have already been performed before that step. With respect to Pani et al statement regarding "the cell becoming white" this relates to the cryopreservation process and not to the washing of plant cells which have already been thawed or the washing of thawed plant cells. The claims remain prima facie obvious over the cited prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously submitted PTO-892. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
Deborah K. Ware
Examiner
Art Unit 1651

/David M. Naff/
Primary Examiner, Art Unit 1657